FY 2013 Budget Overview

The fiscal year (FY) 2013 President's Budget request for FDA is $4,486,368,000. This amount is the FDA total program level, which includes all budget authority, current law user fees, and new proposed user fees.

The FY 2013 budget requests a total program level increase of $654,164,000 above the amount enacted into law for FY 2012. The FY 2013 total for user fees is $1,969,057,000, which includes $583,367,000 in proposed new user fees. The FY 2013 increase in budget authority is $11,502,000.

The following information summarizes the FDA budgets for fiscal years 2011, 2012 and 2013.

FY 2013 Overview Table
Food and Drug Administration
(Dollars in Thousands)

	FY 2011 Enacted [2]	2011 Actuals[3]	2012 Enacted	FY 2013 Request	+/- FY 2012 Enacted
Total Program [1]	**$3,690,481**	**$3,339,281**	**$3,832,204**	**$4,486,368**	**$654,164**
User Fees	**$1,233,480**	**$879,434**	**$1,326,395**	**$1,969,057**	**$642,662**
Budget Authority	**$2,457,001**	**$2,459,847**	**$2,505,809**	**$2,517,311**	**$11,502**
FTE	**12,950**	**13,151**	**13,496**	**14,648**	**1,151**

[1] FY 2011, FY 2012 and FY 2013 do not include an estimated 114 reimbursable, 22 PEPFAR, 44 IDDA FTE and the associated funds.

[2] FY 2011 Enacted reflects the -0.2% rescission pursuant to P.L. 112-10.

[3] FY 2011 Actuals include $88,000 in funds from the $2,000,000 Gulf Oil Spill supplemental appropriation.

FDA FY 2013 Budget Request

The initiatives and resources for FY 2013 will allow FDA to achieve fundamental public health priorities in the following areas:

A. Protecting Patients
+$363,669,000 / 593 FTE

This initiative proposes new user fees to support FDA generic drug activities and to improve generic drug review performance. FDA is also proposing new user fees to support the development and review of biosimilar products, which are structurally and therapeutically similar to biological products manufactured by an innovator.

FDA is also proposing to increase its capacity to detect and address the risks of drugs and drug ingredients manufactured in China to assure that they do not result in harm to Americans. Finally, the FDA budget also contains new

resources to equip state-of-the-art laboratory facilities on the FDA White Oak, Maryland, campus that will support essential research to protect patients and consumers.

B. Transforming Food Safety
+$253,359,000 / 355 FTE

The Transforming Food Safety Initiative will bolster FDA efforts to build a strong, reliable food safety system to protect American consumers, as envisioned in the landmark FDA Food Safety Modernization Act of 2011 (FSMA). Supported by food safety investments commenced during FY 2011 and FY 2012, the user fee resources in this FY 2013 initiative will allow FDA to continue to establish a prevention-focused domestic and import food safety system.

FDA is also requesting budget authority to increase its capacity to detect and address the risks of foods and food ingredients manufactured in China and to assure that they do not result in harm to Americans. In this initiative, FDA is also proposing new user fee programs to support the cosmetic and food contact substance programs.

C. Advancing Medical Countermeasures
+$3,510,000 / 7 FTE

The FDA Medical Countermeasures Initiative (MCMi) is designed to meet America's national security and public health requirements for MCM readiness. In advance of Congress' FY 2012 appropriation for the MCMi, FDA received an allocation of one-time funding at the close of FY 2010 to immediately commence MCMi activities. With these funds, FDA established a base program at its current operating level of 77 FTE.

The FY 2013 budget will allow FDA to sustain the current level of staffing and activities for the MCMi. With these FY 2013 resources, FDA will support partnerships with industry, academia, and with government partners to shorten MCM development timelines and improve the success rate for MCMs. FDA will also expand technical assistance to developers, focusing on the highest priority MCMs.

D. Data Consolidation and IT Savings
- $19,706,000 / - 0 FTE

FDA made significant progress in recent years to consolidate into two modern data center facilities. During the consolidation, FDA modernized and standardized its hardware and software infrastructure. This effort provides an

FDA computing environment that reduces FDA costs for environment setup and support and provides agility not previously possible. The result has been savings in power consumption and the ability to use FDA equipment and IT support resources more efficiently.

Under this FY 2013 initiative, FDA will realize savings that flow from the consolidation effort. These savings also meet the requirements of Executive Orders 13589 (Promoting Efficient Spending) and 13514 (Federal Leadership in Environmental, Energy, and Economic Performance).

E. FDA Current Law User Fees
+$59,295,000 / +196 FTE

FDA user fee programs support safe and effective review for human and animal drugs, biological products, medical devices and the review of other FDA-regulated products. User fees also allow FDA programs to achieve enhanced premarket review performance. Other FDA user fees support the regulation of tobacco products, the inspection of mammography facilities, the certification of color additives, and the certification of FDA-regulated products exported from the United States. Finally, new user fees enacted by the FDA Food Safety Modernization Act support essential food safety activities. The budget request includes inflationary increases for FDA user fee programs, as authorized by law.

Details of the FDA FY 2013 Initiatives

The FDA Congressional Budget Justification contains business case papers justifying the funding increases described above. Within each business case paper, FDA identifies the need for the FY 2013 funding, the activities that FDA will conduct, and the performance that FDA will achieve.